

IN THE CLAIMS:

Please cancel claims 31-37. Please amend claims 1-5, 7, 8, 10, 12-18, 20, 21, 23-27, 29 and 30 as follows:

1. (Currently Amended) A body insertable treatment device, ~~including~~ comprising:

an elongate delivery member having a proximal end region and a distal end region, maneuverable transluminally to position the distal end region at a treatment site within a body lumen;

a treatment fluid delivery means ~~including~~ comprising a treatment sheath having a proximal and a distal end mounted to the delivery member along the distal end region, enlargeable radially into a substantially conforming contact with surrounding tissue at the treatment site during which the sheath provides a compartment for containing a treatment fluid, said sheath further being adapted to allow passage of the treatment fluid from within the compartment to the surrounding tissue during said contact;

said treatment fluid delivery means further ~~including~~ comprising a means for supplying the treatment fluid under pressure to the compartment to move the sheath radially into said contact, to maintain said contact, and to provide the treatment fluid for said passage; ~~and~~

a tissue dilatation means ~~mounted to the delivery member and disposed within said compartment,~~ the dilatation means being enlargeable radially to act radially upon the surrounding tissue through the treatment sheath and thereby effect a dilatation of the surrounding tissue; and

wherein the dilatation ~~means~~ and the treatment sheath are not coupled to one another at any point mounted to the delivery member independent from one another to allow radial movement of the treatment sheath into said contact without radially enlarging the dilatation means, and to allow radial contraction of the dilatation means while maintaining the treatment sheath in said contact.

2. (Currently Amended) The device of claim 1 wherein:

said treatment fluid delivery means further comprises an elongate and flexible catheter having a first lumen open to the proximal end region of the catheter and to the compartment.

3. (Currently Amended) The device of claim 2 wherein:

said dilatation means further comprises a substantially inelastic and fluid impermeable dilatation balloon cooperating with the catheter to form a dilatation chamber fluid isolated from the compartment, and wherein the catheter further has a second lumen open to the proximal end region of the catheter, open to the dilatation chamber, and fluid isolated from the first lumen.

4. (Currently Amended) The device of claim 3 further ~~including~~ comprising:

a dilatation fluid source for providing a dilatation fluid under pressure to the dilatation chamber via the second lumen, and a treatment fluid source fluid coupled to the first lumen.

5. (Currently Amended) The device of claim 1 further ~~including~~ comprising:

a lumen running substantially the length of the delivery member for accommodating a guidewire.

6. (Original) The device of claim 3 wherein:

said dilatation balloon surrounds the catheter, and is joined to the catheter by proximal and distal fluid tight balloon couplings.

7. (Currently Amended) The device of claim 6 wherein:

said treatment sheath surrounds the dilatation balloon and is joined to the catheter by proximal and distal fluid tight sheath couplings.

8. (Currently Amended) The device of claim 1 wherein:

said treatment sheath is formed of a biocompatible elastomeric material.

9. (Original) The device of claim 8 wherein:

said biocompatible elastomeric material consists essentially of at least one of the following: latex, urethane, silicone, and a thermoplastic elastomer.

10. (Currently Amended) The device of claim 8 wherein:

the biocompatible elastomer has a modulus of elasticity in the range of 2,000 to 80,000 psi, said sheath has a uniform thickness in the range of 0.5-5 mils, whereby the treatment sheath elastically expands into said substantially conforming contact.

11. (Original) The device of claim 8 wherein:

said biocompatible elastomeric material is porous.

12. (Currently Amended) The device of claim 11 wherein:

said treatment sheath has a uniform thickness of at most about 2.0 mils.

13. (Currently Amended) The device of claim 8 wherein:

said biocompatible elastomeric material is substantially impervious to fluids, and wherein multiple pores having diameters in the range of 15-100 microns are formed through the treatment sheath to allow said passage of the treatment fluid.

14. (Currently Amended) A treatment system ~~including~~ comprising the device of claim 1, and further ~~including~~ comprising:

a first lumen through the delivery means and open to the compartment, and a first control means to govern a first fluid pressure at which the treatment fluid is provided to the compartment via the first lumen;

a dilatation fluid source, a second lumen through the catheter open to the dilatation chamber, and a second control means to govern a second fluid pressure at which the dilatation fluid is provided from the dilatation fluid source to the dilatation chamber via the second lumen;
and

a third lumen through the delivery member, and a guidewire adapted for intravascular insertion to position a distal end thereof near the treatment site, with a proximal end thereof adapted for receipt into a distal end of said third lumen to facilitate a distal advance of the delivery member over the guidewire toward the treatment site.

15. (Currently Amended) The device of claim 1 further ~~including~~ comprising:

a fluid passage means in said delivery member and open to the catheter exterior near the treatment site when the treatment sheath is in said substantially conforming contact, to allow a flow of body fluids within the body lumen through the delivery member past the treatment site.

16. (Currently Amended) A process for treating tissue at a treatment site within a body lumen, ~~including~~ comprising:

intraluminally advancing an elongate flexible catheter until a flexible treatment sheath mounted to a distal end region of the catheter is adjacent a predetermined treatment site; and

supplying a treatment fluid under pressure to a compartment formed by the treatment sheath, to (i) elastically expand the treatment sheath radially into a substantially conforming contact with the surrounding tissue at the treatment site, (ii) cause the treatment fluid to pass through the treatment sheath from the compartment to the surrounding tissue, and (iii) maintain the treatment sheath expanded into said contact.

17. (Currently Amended) The process of claim 16 further ~~including~~ comprising:

while maintaining the sheath in said intimate and substantially conforming contact, radially expanding a tissue dilatation means within the compartment until the dilatation means engages the treatment sheath, then further radially expanding the dilatation means whereby the dilatation means acts radially upon the surrounding tissue through the treatment sheath to effect a dilatation of the surrounding tissue;

following said dilatation, radially contracting the dilatation means while maintaining the treatment sheath in said contact to administer the treatment fluid to the dilated tissue; and

following said administering of the treatment fluid, discontinuing the supplying of the treatment fluid to allow the treatment sheath to radially contract under a residual elastic force.

18. (Currently Amended) The process of claim 17 further ~~including~~ comprising:

after allowing the treatment sheath to radially contract, proximally withdrawing the catheter from the body lumen.

19. (Original) The process of claim 16 wherein:

said advancing of the catheter includes intraluminally positioning a guidewire with a distal end thereof outside of the body, inserting the proximal end of the guidewire within the distal end of a guidewire lumen running through the catheter, and advancing the catheter distally relative to the guidewire.

20. (Currently Amended) The process of claim 16 wherein:

said supplying of the treatment fluid includes ~~providing~~ comprising the treatment fluid to the compartment via treatment fluid supply lumen of the catheter at a predetermined treatment fluid pressure.

21. (Currently Amended) The process of claim 20 wherein:

said supplying of the treatment fluid ~~includes~~ comprises causing the treatment fluid to perfuse through multiple pores in said treatment sheath.

22. (Original) The process of claim 17 wherein:

said dilatation means comprises a dilatation balloon formed of a substantially inelastic material and radially enlargeable by supplying a dilatation fluid to a dilatation chamber formed by the balloon and the catheter, and wherein said contraction of the dilatation means comprises withdrawing the dilatation fluid from the dilatation chamber to substantially evacuate the dilatation balloon.

23. (Currently Amended) The process of claim 17 wherein:

said allowing the treatment sheath to radially contract comprises withdrawing the treatment fluid from the compartment.

24. (Currently Amended) The process of claim 16 further ~~including~~ comprising:

while maintaining the treatment sheath in said substantially conforming contact, allowing a flow of body fluids through the catheter past the treatment site.

25. (Currently Amended) A device for delivering a treatment fluid at an intraluminal treatment site, including comprising:

an elongate delivery catheter having a proximal end region and a distal end region, maneuverable transluminally to position the distal end region at a treatment site within a body lumen;

a treatment sheath mounted to the catheter along the distal end region and expandable radially into a substantially conforming contact with surrounding tissue at the treatment site, said sheath while elastically expanded cooperating with the delivery member to form a compartment for containing a treatment fluid, the sheath further being adapted to allow passage of the treatment fluid from within the compartment to the surrounding tissue during said contact;

a tissue dilatation means mounted to the catheter along the distal end region and disposed within said compartment, radially enlargeable from a reduced radius delivery state to a radially enlarged state for acting radially upon the surrounding tissue through the sheath to effect a dilatation of the surrounding tissue;

a treatment fluid supply means for providing the treatment fluid under pressure to the compartment to enlarge the sheath radially while said tissue dilatation means remains in the delivery state, to move the sheath radially into said contact and maintain said contact, and further to maintain a supply of the treatment fluid within the compartment during said contact and said passage of the treatment fluid; and

a dilatation control means for radially enlarging the dilatation means and for radially contracting the dilatation means toward the delivery state while said contact is maintained, wherein the dilatation means and the treatment sheath are not coupled to one another at any point.

26. (Currently Amended) The device of claim 25 further including comprising:

a fluid passage means through the catheter and open to an exterior of the catheter on opposite sides of the treatment sheath, for allowing a flow of body fluids within the body lumen past the treatment site while the treatment sheath is in said substantially conforming contact.

27. (Currently Amended) The device of claim 25 wherein:

the dilatation means further comprises a substantially inelastic dilatation balloon cooperating with the catheter to form a dilatation chamber, and a balloon inflation lumen in the catheter open to the chamber for supplying a dilatation fluid under pressure to the chamber.

28. (Original) The device of claim 27 wherein:

the dilatation balloon surrounds the catheter and is mounted to the catheter by fluid tight proximal and distal couplings.

29. (Currently Amended) The device of claim 28 wherein:

said treatment sheath surrounds the dilatation balloon and is fixed to the catheter at first and second fluid tight sheath couplings on opposite side of the dilatation balloon and spaced apart from the dilatation balloon.

30. (Currently Amended) The device of claim 25 further ~~including~~ comprising:

a guidewire lumen running substantially the length of the catheter and having a distal end for receiving a guidewire to facilitate a distal pushing of the catheter over the guidewire following an intraluminal positioning of the guidewire.

31-37 (Canceled)